

NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

# ENZYMATIC THERAPY' & PHYTOPHARMICA'

**ENZYMATIC THERAPY** 

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like™

December 8, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise  – The Goodness of Purple	Boosts memory function.*	Vitamin C (from acerola cherry fruit extract and sodium ascorbate), Fruit and Vegetable Blend: cranberry fruit, whole apple, strawberry fruit, blueberry fruit, acerola cherry fruit extract, elderberry fruit, blackberry fruit, concord grape fruit, cranberry fruit extract, pomegranate fruit, raspberry fruit, sweet cherry fruit extract, eggplant fruit, bilberry fruit extract, mangosteen fruit, prune fruit extract, whole red bell pepper, Fiber Blend: inulin from chicory root, guar gum seed extract, Stevia Leaf Extract, Proprietary Antioxidant Fruit Blend: grape fruit, grape seed, blueberry fruit, raspberry fruit, raspberry seed, bilberry fruit extracts, cranberry, plum, strawberry, tart cherry fruits, Anthocyaninis (from Fruit and Vegetable Blends), Ellagic Acid (from Fruit and Vegetable Blends), Quercetin (from Fruit and Vegetable Blends)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	KTAGI	LŁ
J		

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

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LET 17094

Michael P. Devereux

Chief Operations Officer



## **ENZYMATIC THERAPY**

INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica
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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582 8386 F: 503.582.0467

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise  – The Goodness of Purple	Helps maintain urinary tract health.*	Vitamin C (from acerola cherry fruit extract and sodium ascorbate), Fruit and Vegetable Blend: cranberry fruit, whole apple, strawberry fruit, blueberry fruit, acerola cherry fruit extract, elderberry fruit, blackberry fruit, concord grape fruit, cranberry fruit extract, pomegranate fruit, raspberry fruit, sweet cherry fruit extract, eggplant fruit, bilberry fruit extract, mangosteen fruit, prune fruit extract, whole red bell pepper, Fiber Blend: inulin from chacory root, guar gum seed extract, Stevia Leaf Extract, Proprietary Antioxidant Fruit Blend: grape fruit, grape seed, blueberry fruit, raspberry fruit, raspberry seed, bilberry fruit extracts, cranberry, plum, strawberry, tart cherry fruits, Anthocyaninis (from Fruit and Vegetable Blends), Ellagic Acid (from Fruit and Vegetable Blends)

l certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	fillilt
	Robert Doster
Title:	Senior Vice President of Scientific Affairs

Date: 12-8-05

Sincerely,



## ENZYMATIC THERADY

#### INTEGRATIVE THERAPEUTICS INC."

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise  - The Goodness of Purple	Supports healthy aging.*	Vitamin C (from acerola cherry fruit extract and sodium ascorbate), Fruit and Vegetable Blend: cranberry fruit, whole apple, strawberry fruit, blueberry fruit, acerola cherry fruit extract, elderberry fruit, blackberry fruit, concord grape fruit, cranberry fruit extract, pomegranate fruit, raspberry fruit, sweet cherry fruit extract, eggplant fruit, bilberry fruit extract, mangosteen fruit, prune fruit extract, whole red bell pepper, Fiber Blend: inulin from chicory root, guar gum seed extract, Stevia Leaf Extract, Proprietary Antioxidant Fruit Blend: grape fruit, grape seed, blueberry fruit, raspberry fruit, raspberry seed, bilberry fruit extracts, cranberry, plum, strawberry, tart cherry fruits, Anthocyaninis (from Fruit and Vegetable Blends), Ellagic Acid (from Fruit and Vegetable Blends), Quercetin (from Fruit and Vegetable Blends)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	flecht
Title:	Robert Doster Senior Vice President of Scientific Affairs
Date:	12-8-05

Sincerely,



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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise  — The Goodness of Purple	The rich, vibrant colors of fruits and vegetables aren't just for decoration. They're nature's way of telling you that these foods are bursting with a wide range of vitamins, nutrients and phytonutrients – naturally occurring, plant-based antioxidants that support a vast array of health benefits ranging from immune to heart to vision health and much more.*	Vitamin C (from acerola cherry fruit extract and sodium ascorbate), Fruit and Vegetable Blend: cranberry fruit, whole apple, strawberry fruit, blueberry fruit, acerola cherry fruit extract, elderberry fruit, blackberry fruit, concord grape fruit, cranberry fruit extract, pomegranate fruit, raspberry fruit, sweet cherry fruit extract, eggplant fruit, bilberry fruit extract, mangosteen fruit, prune fruit extract, whole red bell pepper, Fiber Blend: inulin from chicory root, guar gum seed extract, Stevia Leaf Extract, Proprietary Antioxidant Fruit Blend: grape fruit, grape seed, blueberry fruit, raspberry fruit, raspberry seed, bilberry fruit extracts, cranberry, plum, strawberry, tart cherry fruits, Anthocyaninis (from Fruit and Vegetable Blends), Ellagic Acid (from Fruit and Vegetable Blends), Quercetin (from Fruit and Vegetable Blends)

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Ву:	kullult
	Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

Sincerely,



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Purple	Helps promote healthy memory function.*	Anthocyaninis (from Fruit and Vegetable Blends)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincercly,



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Purple	Supports the immune system.*	Vitamin C (from acerola cherry fruit extract and sodium ascorbate)

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By: KIICILI

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

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Sincerely,

Chief Operations Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Purple	Supports the immune system and healthy cell development.*	Ellagic Acid (from Fruit and Vegetable Blends)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

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PRODUCT NAME	STATEMENTS 4	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise -	Naturally protective	Vitamin C (from acerola cherry fruit extract and sodium
The Goodness of	antioxidants that support	ascorbate), Fruit and Vegetable Blend: cranberry fruit,
Purple	healthy aging and give fruits	whole apple, strawberry fruit, blueberry fruit, acerola
	and vegetables their	cherry fruit extract, elderberry fruit, blackberry fruit,
	coloring.*	concord grape fruit, cranberry fruit extract, pomegranate
	_	fruit, raspberry fruit, sweet cherry fruit extract, eggplant
		fruit, bilberry fruit extract, mangosteen fruit, prune fruit
		extract, whole red bell pepper, Fiber Blend: inulin from
		chicory root, guar gum seed extract, Stevia Leaf Extract,
		Proprietary Antioxidant Fruit Blend: grape fruit, grape
		seed, blueberry fruit, raspberry fruit, raspberry seed,
		bilberry fruit extracts, cranberry, plum, strawberry, tart
		cherry fruits, Anthocyaninis (from Fruit and Vegetable
		Blends), Ellagic Acid (from Fruit and Vegetable Blends),
		Quercetin (from Fruit and Vegetable Blends)

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By:	Kild l'Ilit		
•	Robert Doster Senior Vice President of Scientific Affairs		
Date:	12-9-05		

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Purple	Helps maintain a healthy heart*	Quercetin (from Fruit and Vegetable Blends)

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By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

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Chief Operations Officer

Earth's Promise Purple 11e